

510(k) Summary for
Modifications to the Diomed Surgical Diode Laser

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1. Date Summary Prepared

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2. Submitter's Name and Address

Surgimedics/ESP
2828 N. Crescent Ridge Drive
The Woodlands, TX 77381

Contact Person: Mr. Donald F. Hults
Phone Number: (713) 363-4949
Fax Number: (713) 298-7930

3. Device Name

Trade/Proprietary Name: Diomed 15 Surgical Diode Laser
Diomed 30 Surgical Diode Laser
Diomed 60 Surgical Diode Laser
Common Name: Laser, GaAlAs - Diode

4. Predicate Device

The legally marketed device to which equivalence is being claimed is:

Diomed 25 Surgical Diode Laser

5. Device Description

The Diomed Surgical Diode Laser is a Class IV GaAlAs (Gallium Arsenide) diode laser with a wavelength of 805nm and a visible (aiming beam) 5 milliwatt Class IIIa diode laser with a wavelength of 650nm.

The Diomed 15/30/60 Watt Surgical Diode Lasers are modifications to the maximum power output rating of the original Diomed 25 Watt Diode Surgical Laser. The modifications are in three areas:

Labeling: The Diomed 25 Surgical Diode Laser will be renamed (reabeled) to the Diomed 30 Surgical Diode Laser. This change is being made to be consistent with the industry practice of designating a laser's power based on the output power at the laser port rather than at the tissue site. There is no change in construction or performance of this device.

Power Output: Two additional models will be created by doubling and halving the output power to produce the Diomed 15 15W Surgical Diode Laser and the Diomed 60 60W Surgical Diode Laser, respectively. The same basic design is retained. The 15 Watt model uses eight 2 Watt laser diodes, the 30 Watt model uses sixteen 2 Watt laser diodes, and the 60 Watt model uses sixteen 4 Watt laser diodes. The power supply and cooling designs of the new models have been appropriately scaled, while the mechanical design and user interface remain unchanged.

Indication For Use: The indications for the three models are expanded to include both contact and non-contact use for the following soft tissue applications:

- General Surgery
- Ophthalmology/Oculoplastic
- Urology
- Gastroenterology
- Gynecology
- Otorhinolaryngology
- Pulmonary/Thoracic
- Dermatology/Plastic Surgery
- Neurosurgery (coagulation only)
- Orthopedic

6. **Intended Use**

The Diomed Surgical Diode Laser is intended for use in delivering 15, 30, or 60 Watts of continuous wave radiation to a flexible optical fiber, for use in ablation, incision, excision, coagulation, and vaporization of soft tissue in open and endoscopic surgical procedures.

7. **Comparison of Technological Characteristics**

The modification replaces the Diomed 25 Surgical Diode Laser with three new models, the Diomed 15, 30, and 60 Surgical Diode Lasers. Modifications are to offer models with different maximum output powers (15, 30, and 60 Watts at the output port), in order to provide sufficient power when it is required, and to provide a more cost effective device for applications that do not require the higher power capabilities. The Diomed 25 Surgical Diode Laser currently operates with a maximum output power of 30 Watts at the output port. In addition indications for use have been expanded to include both contact and non-contact treatment of soft tissues applications for which legally marketed lasers are currently available.

8. **Nonclinical Tests Used in Determination of Substantial Equivalence**

The design of the Diomed surgical Diode Lasers has been thoroughly validated at the unit and system level. The tests showed that all system specifications are satisfied.

Canine tissue studies demonstrate equivalent performance between the Diomed Surgical Diode Laser and predicate laser systems, and concludes that tissue damage effects of the Diomed Surgical Diode Laser do not exceed those of existing Nd:YAG lasers.

9. **Conclusions From Nonclinical Testing**

The testing of the modified devices demonstrates that the performance is substantially equivalent to the predicate device prior to the modifications.